

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 18 JUL 2005

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Applicant's or agent's file reference 4439PTWO/AG/la	<b>FOR FURTHER ACTION</b>	
		See Form PCT/IPEA/416
International application No. PCT/EP2004/008572	International filing date (day/month/year) 30.07.2004	Priority date (day/month/year) 31.07.2003
International Patent Classification (IPC) or national classification and IPC A61K7/48, A61K31/13, A23L1/305, A61P17/00		
Applicant GIULIANI S.P.A		

<ol style="list-style-type: none"> <li>This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</li> <li>This REPORT consists of a total of 5 sheets, including this cover sheet.</li> <li>This report is also accompanied by ANNEXES, comprising:           <ol style="list-style-type: none"> <li><input type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of sheets, as follows:               <ul style="list-style-type: none"> <li><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</li> <li><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</li> </ul> </li> <li><input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)), containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</li> </ol> </li> </ol>																
<ol style="list-style-type: none"> <li>This report contains indications relating to the following items:           <table border="0"> <tr> <td><input checked="" type="checkbox"/> Box No. I</td> <td>Basis of the opinion</td> </tr> <tr> <td><input type="checkbox"/> Box No. II</td> <td>Priority</td> </tr> <tr> <td><input type="checkbox"/> Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/> Box No. IV</td> <td>Lack of unity of Invention</td> </tr> <tr> <td><input checked="" type="checkbox"/> Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/> Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/> Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/> Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table> </li> </ol>	<input checked="" type="checkbox"/> Box No. I	Basis of the opinion	<input type="checkbox"/> Box No. II	Priority	<input type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/> Box No. IV	Lack of unity of Invention	<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/> Box No. VI	Certain documents cited	<input type="checkbox"/> Box No. VII	Certain defects in the international application	<input type="checkbox"/> Box No. VIII	Certain observations on the international application
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<input type="checkbox"/> Box No. VIII	Certain observations on the international application															

Date of submission of the demand  12.05.2005	Date of completion of this report  19.07.2005
Name and mailing address of the International preliminary examining authority:   European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer  Minas, S Telephone No. +31 70 340-3936



**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/EP2004/008572

**Box No. I Basis of the report**

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
  - This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
    - international search (under Rules 12.3 and 23.1(b))
    - publication of the international application (under Rule 12.4)
    - international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

**Description, Pages**

1-6 as originally filed

**Claims, Numbers**

1-8 as originally filed

a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3.  The amendments have resulted in the cancellation of:
  - the description, pages
  - the claims, Nos.
  - the drawings, sheets/figs
  - the sequence listing (*specify*):
  - any table(s) related to sequence listing (*specify*):
4.  This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
  - the description, pages
  - the claims, Nos.
  - the drawings, sheets/figs
  - the sequence listing (*specify*):
  - any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/EP2004/008572

**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes:	Claims	5,6
	No:	Claims	1-4,7,8
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-8
Industrial applicability (IA)	Yes:	Claims	1-8
	No:	Claims	

**2. Citations and explanations (Rule 70.7):**

**see separate sheet**

**INTERNATIONAL PRELIMINARY  
REPORT ON PATENTABILITY  
(SEPARATE SHEET)**

International application No.

PCT/EP2004/008572

**Re Item V**

**Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Reference is made to the following documents:

- D1: US-A-4 507 321 (RAISFELD ILENE H) 26 March 1985 (1985-03-26)
- D2: WO 94/12464 A (CHARONIS ARISTIDIS S ; FURCHT LEO T (US); CANELLAKIS EVANGELO (GR); TS) 9 June 1994 (1994-06-09)
- D3: WO 99/51213 A (ILENCHUK THEODORE TONEY ; MADDIN WILLIAM STUART (CA)) 14 October 1999 (1999-10-14)
- D4: EP-A-0 884 046 (LEE DE NV SARA) 16 December 1998 (1998-12-16)
- D5: WO 98/06376 A (REVOL CONSUMER PROD CORP) 19 February 1998 (1998-02-19)
- D6: WO 96/23490 A (HAHN GARY SCOTT ; COSMEDERM TECHNOLOGIES (US); THUESON DAVID OREL (US)) 8 August 1996 (1996-08-08)
- D7: PATENT ABSTRACTS OF JAPAN vol. 2003, no. 08, 6 August 2003 (2003-08-06) & JP 2003 113047 A (TOSHIN KAGAKU KK), 18 April 2003 (2003-04-18)
- D8: DATABASE WPI Section Ch, Week 199550 Derwent Publications Ltd., London, GB; Class B07, AN 1995-390534 XP002046837 & JP 07 268323 A (NISSHIN OIL MILLS LTD) 17 October 1995 (1995-10-17)

**V.1 Novelty (Article 33(2) PCT)**

*If a known product is in a form, in which it is in fact suitable for the stated use, though it has never been described for that use, would deprive the claim of novelty.*

Document D1 discloses in claim 1 a method for stimulating cell renewal by the use of an aliphatic di-and polyamine, preferably spermine or spermidine (see examples).

The subject matter of claims 1-4,7 and 8 is therefor **not new**.

Document D2 suggests on page 11 lines 20-22 the oral administration or the topical use of polyamines, preferably spermine or spermidine (see claims), as *anti-ageing formulations* in order to prevent tissue ageing and degradation, which results in an improved elasticity of the skin. The subject matter of claims 1-4,7 and 8 is therefor **not new**.

Document D3 deals with the use of spermine and spermidine (see examples and claims) in the treatment of dermatological symptoms, thereby revealing their activity in cell renewal. The subject matter of claims 1-4,7 and 8 is therefor **not new**.

**INTERNATIONAL PRELIMINARY  
REPORT ON PATENTABILITY  
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**PCT/EP2004/008572**

Document D4 discloses synergistic effects of the combination of spermine or spermidine with vitamin C and E in photoprotective compositions against UV radiation for preventing skin ageing which results in loss of *elasticity* and *moisture* in the skin (see e.g. paragraph 2, left column, first page). The subject matter of claims 1-4 and 8 is therefor **not new**.

Document D5 discloses nail strengthening compositions comprising spermine as conditioning agent (p.10,l.1-29; claims 18-20). The subject matter of claims 3,4 and 8 is therefor **not new**.

Document D6 discloses in claims 1 and 2 topical compositions for treating skin irritations attributable to dry skin (claim 93) comprising spermine or spermidine. The subject matter of claims 1-4 and 8 is therefor **not new**.

Document D7 discloses a conditioning hair cosmetics comprising spermine or spermidine. The subject matter of claims 3,4 and 8 is therefor **not new**.

Document D8 discloses pharmaceuticals, feed and cosmetics comprising spermine or spermidine as antioxidants. The subject matter of claims 3,4 and 8 is therefor **not new**.

**V.2 Inventive step (Article 33(3) PCT)**

The documents D1-D3 appear to be of particular relevance as far as inventive step is concerned. These documents use indeed the same solution to solve the same problem as the present application, namely to combat signs of skin ageing by the use of spermine and/or spermidine. So apparently, the present application does not fulfill the requirements of Article 33(3) PCT over this prior art document.